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VASCULAR BLOOD SAMPLING CATHETER**RELATED APPLICATION DATA**

This application claims priority from U.S. Provisional Patent Application Ser. No. 61/722,160, filed 3 Nov. 2012.

FEDERALLY SPONSORED RESEARCH

Not Applicable

SEQUENCE LISTING OR PROGRAM

Not Applicable

BACKGROUND OF THE INVENTION**1. Field of the Invention**

This invention relates to liquid sampling catheters such as vascular catheters, specifically in their use to sample volumes of patient liquids, including blood, in clinical settings.

2. Background of the Art

The embodiments described herein relate generally to medical devices. More particularly, the present disclosure relates to a blood sampling device and associated method via a vascular access device. Blood sampling is a common medical procedure involving the withdrawal of at least a drop of blood from a patient. Hospitals, medical clinics, emergency rooms, and health care providers commonly sample liquid from patients either by lancet fingerstick or heel stick devices, venipuncture, or central IV lines. Once collected, blood samples are analyzed via a variety of chemistry tests.

Blood samples are commonly taken to determine the physiological and biochemical state of a patient, and are either analyzed in a laboratory, a distance away from a patient, or at the point of care, near the location of the patient. Clinicians then use this analysis to determine the disease state of a patient, mineral concentrations, organ function, and clinical treatment effectiveness. One example of a common blood test is a point of care blood glucose test, where blood is extracted via a lancet fingerstick, and mechanically transferred onto a testing strip to determine blood glucose values. In other tests, clinicians draw a vial of blood from a venous or arterial source, and then that sample is analyzed in a central laboratory for tens to hundreds of biochemical tests including gas electrolyte levels, protein analysis, and cholesterol quantification, among others.

Despite rapid advancements in both laboratory analysis and point of care testing, current methods of blood sampling have remained relatively unchanged. Each of these methods presents their own unique challenges and issues. Lancets sample capillary blood, which has a higher margin of error in metabolic measurements. These devices also cause discomfort as patients are continually pricked. Venipuncture, the most common method of sampling, when done frequently can cause significant trauma to the venous system and impede the integrity of a patient's veins. Additionally, venipuncture is a manual, labor-intensive process creating significant labor costs by requiring specially trained venipuncture teams within hospitals. It also presents a much higher level of discomfort than lancets. Central line sampling is a more complicated procedure with multiple steps and can be prone to error. Using the same site for infusion and sampling causes an increased chance of sample contamination. Drawing blood from central lines is also known to increase the risk of central line-associated blood stream infections. These blood sampling processes are labor and time intensive, and require

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multiple devices throughout the sampling process. Furthermore, these methods have many clinical and practical problems associated with their use. Accordingly, there is a need for more efficient and accurate blood sampling devices.

U.S. Pat. No. 8,366,685 (Devgon) describes systems and methods for phlebotomy through a peripheral IV catheter. An actuator is used to advance and retract a sampling cannula that engages a peripheral intravenous line.

US Patent Application (abandoned) Pub. No.: US 2002/0120215 A1, describes a BLOOD COLLECTION SET WITH RETRACTABLE NEEDLE (Crawford) that provides a retractable sheath over a needle sampler, the sheath having horizontal stabilizing wings.

SUMMARY OF THE INVENTION

An embodiment of the present invention provides a medical blood sampling device and related method for sampling of blood from the vascular system of the patient. An embodiment of the present invention provides a medical blood sampling device and related method that, among other things, facilitates quick, simple, and standardized sampling of the blood sources considered most clinically acceptable. This innovation improves the accuracy, patient comfort, and convenience associated with blood draws.

The ability to sample blood accurately and noninvasively is imperative in conserving blood and yielding more accurate analyte test results, which leads to improvements in patient outcomes and comfort. The device herein established will provide a standardized and simple means to obtain these blood samples. This will improve patient comfort and potentially their overall clinical outcome.

This technology is provided by structures and/or methods that may implement the sampling of liquids from within a patient with at least steps of:

- a) inserting a sampling device into a region of a patient, the sampling device comprising a delivery catheter and within a lumen of the delivery catheter is a sampling cannula having a longitudinal axis, the delivery catheter being moveable over the sampling cannula by retraction or extension of the delivery catheter sheath(s);
- b) moving the delivery catheter towards a target area within the patient (which may contain a distal volume of material from which a sample is to be taken) causes the delivery catheter to press against the patient or sampling hub thereby causing the sheath(s) of the delivery catheter to retract as the delivery catheter advances forward which exposes the sampling cannula to the target area within the patient
- c) allowing liquid within the target area within the patient into the sampling cannula; and
- d) withdrawing the liquid from the sampling cannula to create a liquid sample.

A general description of the sampling device could include a delivery catheter and within a lumen of the delivery catheter is a sampling cannula having a longitudinal axis, the delivery catheter being moveable over the sampling cannula by retraction or extension. The delivery catheter could also enter the target area through a sampling hub (especially as described herein) or directly through the patient's skin.

A sampling hub directs a medical device towards a target area. The hub may have some of: a hub body; a lumen passing between openings at the front end (distal end) or bottom of the hub and the rear end (proximal end), the lumen allowing for passage of an elongate element through the entire lumen; in one optional structural embodiment, the bottom of the hub body may be flat (or any convenient configuration, including